## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY D/B/A BLUE CROSS AND BLUE SHIELD OF LOUISIANA, HMO LOUISIANA, INC., and DAVID MITCHELL, individually and on behalf of all others similarly situated,

No. 1:23-CV-07871-ER

Plaintiffs,

v.

CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, and JEROME ZELDIS,

Defendants.

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT ANTHONY INSOGNA'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

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#### INTRODUCTION

The Court should dismiss the claims against Anthony M. Insogna, Esq. in full. It is well-settled that lawyers cannot be held liable under the antitrust laws simply for performing legal work for their clients—which is all that Plaintiffs allege Mr. Insogna did.

Nevertheless, after dismissing their antitrust claims against all of the initial defendants in this case except Bristol Myers Squibb and Celgene Corporation (together, "Celgene"), Plaintiffs remarkably added Celgene's outside patent counsel Mr. Insogna as an individual defendant in an amended complaint. They seek to hold Mr. Insogna *personally* liable under the antitrust laws for legal work he did for Celgene over a decade ago, when he represented the company before the U.S. Patent and Trademark Office ("PTO") and helped the company obtain two patents related to its pomalidomide drug POMALYST. As Plaintiffs see it, because Celgene allegedly improperly asserted those and other patents—each of which is entitled to a statutory presumption of validity—years later to maintain a supposed monopoly, Mr. Insogna should be liable for having "participated" in an anticompetitive scheme as one of Celgene's lawyers.

This theory of liability is as groundless as it is far-reaching. Mr. Insogna is not the only lawyer who worked on Celgene's patents related to pomalidomide, but he is the only lawyer that Plaintiffs have chosen to sue here. Between their selective prosecution and patently false accusations about Mr. Insogna's conduct, Plaintiffs' decision to sue him reeks of impropriety. But even accepting their baseless allegations as true for purposes of this motion, the Court should reject Plaintiffs' claims against Mr. Insogna out of hand.

Courts have repeatedly held that a lawyer cannot be held liable under the antitrust laws for legal work done on his client's behalf. Instead, liability can attach only when the lawyer exceeds his role as a legal advisor and *dictates* the client's anticompetitive strategy. Plaintiffs do not and

cannot allege anything like this for Mr. Insogna—much less with the plausibility and specificity that pleading standards require.

Instead, Plaintiffs offer a scattershot of allegations that Mr. Insogna purportedly misled the PTO when helping Celgene secure two patents that Celgene purportedly enforced in an anticompetitive manner years later. But their allegations of "fraud" are demonstrably false, and their attempts to suggest wrongdoing before the PTO are baseless and inaccurate. Regardless, this is not a plausible antitrust claim even against a non-lawyer, when Plaintiffs do not allege in their Amended Complaint that Mr. Insogna played any role in the enforcement of those patents. Moreover, Plaintiffs' attempts to connect Mr. Insogna to some larger "scheme" are implausible on their face, given that his alleged actions predated the FDA's approval of POMALYST® by years, with no plausible factual allegations that Mr. Insogna was "knowingly" involved in a supposed scheme to corner a market on pomalidomide that had yet to exist.

Plaintiffs' claims are also untimely. All parties agree that Plaintiffs' Sherman Act claims are subject to a four-year statute of limitations, but Mr. Insogna's last act alleged in the Complaint took place in 2013, ten years before Plaintiffs added him as a defendant.

In light of their plainly insufficient and scurrilous pleadings, Plaintiffs' addition of Mr. Insogna as a defendant is difficult to understand, as is their puzzling request for injunctive relief against him. But maybe they gave their game away at the pre-motion conference. Recognizing the problems with their claims against Mr. Insogna and the other newly added individual defendant, Dr. Jerome Zeldis, Plaintiffs remarked that "there really isn't a change whether these defendants are removed" from the case—because "whatever decision comes on [them], our sense of discovery will not change." Feb. 22, 2024 Hearing Tr. 19:2-6. Worse, Plaintiffs noted their hope that "discovery will probably only reveal that they need to stay in this case." *Id.* at 19:7-9.

Fishing expeditions are rarely telegraphed so clearly, and Plaintiffs' cavalier attitude is galling. The consequences of joining an individual as a defendant in an antitrust action seeking treble damages are profound—particularly where, as here, Plaintiffs assail Mr. Insogna's professional conduct. Because Plaintiffs' allegations against Mr. Insogna fall well short of stating a claim, the Court should dismiss the claims against him in full.

#### **BACKGROUND**

#### A. The Parties

Celgene sells POMALYST® (in which the active ingredient is pomalidomide), a highly effective treatment for the blood cancer multiple myeloma when combined with dexamethasone in a specific dosing cycle. First Amended Complaint ("FAC") ¶ 1, Dkt. 69. Plaintiffs are a health insurance company, an HMO, and an individual who claim to have overpaid for POMALYST® and seek to represent a putative class of POMALYST® purchasers. *Id.* ¶¶ 6-8.

Plaintiffs filed this suit in September 2023, alleging that Celgene and four generic manufacturers of pomalidomide violated the Sherman Act and state-law analogues by engaging in anticompetitive behavior related to pomalidomide. Dkt. 6 (Complaint). Plaintiffs then dismissed their claims against the generic manufacturers and, in December 2023, amended their complaint to add two new Defendants: Celgene's outside counsel Anthony M. Insogna, Esq., and former Celgene executive Jerome Zeldis, M.D. FAC ¶¶ 11-12.

Plaintiffs accuse Mr. Insogna of monopolization in violation of the antitrust laws based on his role in helping Celgene secure two patents for inventions related to Celgene's research-and-development efforts involving pomalidomide over a decade ago. *Id.* ¶¶ 446-72. Many lawyers worked on these and other patents related to pomalidomide, but Plaintiffs have chosen to sue only Mr. Insogna in this action.

#### B. Factual Background

In November 2002, Celgene filed a provisional patent application for methods of treating refractory or relapsed multiple myeloma, among other cancers. *Id.* ¶ 149. That was the first of a series of patent applications for methods of use involving pomalidomide approved by the PTO, which ultimately granted three multiple myeloma method-of-treatment patents deriving from the November 2002 application: the '262, '3939, and '428 patents. *Id.* ¶¶ 150-51. In May 2009, Celgene separately filed a provisional patent application that led to the granting of the three pomalidomide formulation patents relevant here: the '427, '467, and '5939 patents. *Id.* ¶ 318. Plaintiffs allege that Mr. Insogna was involved in the prosecution of just *two* of these six patents: the '262 method of treatment patent and the '427 formulation patent. *Id.* ¶¶ 164, 207. He is not alleged to have had any role in obtaining the other four patents.

In April 2012, Celgene submitted a New Drug Application ("NDA") for FDA approval to market POMALYST<sup>®</sup>. *Id.* ¶ 198. The FDA approved that application in February 2013. *Id.* ¶ 199. Because POMALYST<sup>®</sup> contained a "new chemical entity" never previously approved by FDA, Celgene was granted a five-year exclusivity period (unrelated to, but concurrent with, patent exclusivity) until February 2018. *Id.* ¶¶ 26, 200.

In February 2017, in anticipation of that five-year period expiring, numerous generic manufacturers filed Abbreviated New Drug Applications ("ANDAs") for pomalidomide drugs that would be generic versions of POMALYST®. *Id.* ¶ 247. Through certain "Paragraph IV" certifications that act as a "technical act of infringement" that "allows a patent owner to sue" before any generic product is launched, *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 144 n.6 (3d Cir. 2017), these ANDAs represented that Celgene's pomalidomide patents either were invalid or would not be infringed by the proposed generic products. In response, Celgene sued the generic manufacturers for patent infringement. FAC ¶ 30-31, 250-51.

In those lawsuits, counsel for the generic manufacturers repeatedly challenged the validity of the pomalidomide patents—but never suggested that Celgene had obtained the patents through fraud or inequitable conduct, even though this would have been a defense to infringement. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc). After years of litigation, including the exchange of invalidity and non-infringement contentions, the parties amicably settled all of these cases. FAC ¶¶ 314, 346, 354, 366-67.

#### C. Plaintiffs' Claims

In this case, Plaintiffs allege that Celgene defrauded the PTO when securing the six pomalidomide patents, such that the enforcement of these patents can give rise to antitrust liability under *Walker Process Equipment, Inc. v. Food Machine & Chemical Corp.*, 382 U.S. 172 (1965). FAC ¶¶ 67, 152, 275, 296, 453.<sup>2</sup> And Plaintiffs allege that Mr. Insogna should be individually liable because he served as Celgene's counsel before the PTO in connection with two of the six patents—the '262 patent, granted in 2012, and the '427 patent, granted in 2014. FAC ¶¶ 194, 215. Plaintiffs assert claims against Mr. Insogna under Section 2 of the Sherman Act and its state-law analogues. *Id.* ¶¶ 446-72.

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<sup>&</sup>lt;sup>1</sup> See Celgene Corp. v. Hetero Labs Ltd., No. 2:17-cv-03387-ES-MAH (D.N.J.) (consolidated with member cases Nos. 2:19-cv-05806, 2:19-cv-05797, 2:19-cv-08758, 2:19-cv-05799, 2:19-cv-05802, 2:19-cv-05804, 2:17-cv-03159, 2:18-cv-14715, 2:19-cv-00143, 2:18-cv-16035, 2:18-cv-14111, 2:18-cv-14366, 2:18-cv-16395, 2:18-cv-02593, 2:20-cv-02593, 2:20-cv-02597, 2:20-cv-02601, 2:20-cv-02606, 2:20-cv-02608, 2:20-cv-02614); Celgene Corp. v. Synthon Pharm. Inc., No. 2:18-cv-10755-ES-MAH (D.N.J.); Celgene Corp. v. Synthon Pharm. Inc., No. 2:19-cv-09737 (D.N.J.); Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd., No. 2:29-cv-15343 (D.N.J.); Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd., No. 2:29-cv-15343 (D.N.J.); Celgene Corp. v. Dr. Reddy's Lab'ys Private Ltd., No. 2:22-cv-01993 (D.N.J.).

<sup>&</sup>lt;sup>2</sup> "[T]he showing required for proving the fraud component of *Walker Process* liability" is "nearly identical" to "the showing required for proving inequitable conduct" as a defense to infringement. *TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016).

Notably, the Complaint does not allege that Mr. Insogna enforced any of the patents. Nor does it allege that Mr. Insogna played any role in Celgene's settlements with the generic manufacturers. Plaintiffs nevertheless seek declaratory and injunctive relief against Mr. Insogna—even though it is unclear why such relief could be appropriate here, when Plaintiffs have not alleged that Mr. Insogna engaged in *any* relevant conduct for the past eleven years—as well as monetary damages.

#### STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege facts sufficient to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although the court accepts all factual allegations in the complaint as true, "[the court is] not required to credit conclusory allegations or legal conclusions couched as factual allegations." *Id.* at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

#### **ARGUMENT**

## I. PLAINTIFFS HAVE NOT STATED A SHERMAN ACT CLAIM AGAINST MR. INSOGNA.

It is exceedingly unusual to hold a lawyer personally liable under the antitrust laws based on actions he took on behalf of his client. As many courts have held, "an attorney may be found individually liable under the antitrust laws *only* if he exceeds his role as legal adviser and becomes an active participant in formulating policy decisions with his client to restrain competition." *Brown v. Donco Enterps.*, 783 F.2d 644, 646 (6th Cir. 1986) (emphasis added). Even with non-lawyers, courts generally decline to impose individual liability for mere participation in a purported anticompetitive scheme and instead require the defendant to have designed the scheme.

Because Plaintiffs have alleged nothing of the sort against Mr. Insogna, the Court should dismiss the claims against him out of hand.

# A. Plaintiffs Make No Allegations That Can Support Imposing Antitrust Liability on Celgene's Outside Counsel.

To begin, Plaintiffs are far afield from stating an adequate basis to hold a lawyer like Mr. Insogna liable under the Sherman Act for actions taken on behalf of his client. In order "to subject an attorney to individual liability under the antitrust laws, the plaintiff must plead and prove that the defendant attorney exerted his power and influence so as to direct the corporation to engage in the complained of acts for an anticompetitive purpose." *Brown*, 783 F.2d at 646-47; *see also Amarel v. Connell*, 102 F.3d 1494, 1522 (9th Cir. 1996) (same). Only through such allegations can a plaintiff allege that a lawyer "exceed[ed] his role as a legal adviser" and became a policymaker for his client. *Brown*, 783 F.2d at 646.

This demanding standard reflects that "attorneys ordinarily act in response to their clients['] directives" instead of as independent economic actors. *Brown*, 783 F.2d at 646; *see also*, *e.g.*, N.Y. Rules Prof. Conduct 1.2(a) (requiring lawyers to "abide by a client's decisions concerning the objectives of representation"). Moreover, "[w]hen acting at the behest of a client, an attorney is *required* to 'resolve in favor of his client doubts as to the bounds of the law." *Brown*, 783 F.2d at 646 (quoting Model Code of Prof. Resp. EC 7-3) (emphasis added). In addition, "in meeting his duty to zealously prosecute his client's case, an attorney may 'urge any permissible construction of the law favorable to his client." *Id.* (citing Model Code of Prof. Resp. EC 7-4). Because of these fundamental ethical obligations—which must guide lawyers' actions in service of their clients—courts have refused to impose antitrust liability on lawyers who did not dictate their clients' supposedly anticompetitive actions.

Thus, in *Brown*, the court dismissed the plaintiffs' antitrust claims against attorney defendants who allegedly "engage[d] in a conspiracy to file and threaten lawsuits . . . so as to coerce, intimidate, and compel plaintiffs and other franchisees to purchase pre-packaged food products exclusively from [the attorneys' clients] at substantially higher prices." 783 F.2d at 645-46. Even though the attorney defendants had "drafted letters and threatened and filed lawsuits in furtherance of the illegal conspiracy"—conduct that was critical to the alleged anticompetitive scheme, and that far exceeds anything alleged against Mr. Insogna—the court dismissed the claims against them because "[t]he complaint did not allege that the attorney defendants served as active participants in formulating the [company's] policy" and, moreover, "did not allege that the attorney defendant stepped beyond their role as legal adviser." 783 F.2d at 646-47.

Other courts agree and have similarly dismissed antitrust claims against lawyers where the complaint "does not allege that these defendants engaged in policy decisions so as to render them liable under the antitrust laws." *Array Holdings Inc. v. Safoco, Inc.*, No. CIV.A. H-12-366, 2013 WL 2617965, at \*1, \*8 (S.D. Tex. June 11, 2013) (dismissing claims against attorneys who negotiated the settlement of a patent infringement suit while allegedly "aware that its terms were illegal"); *see also Amarel v. Connel*, No. C-85-20735-WAI, 1986 WL 10613, at \*3 (N.D. Cal. Aug. 8, 1986) (dismissing claims against attorney where plaintiffs had not pleaded "the conduct, if any, by which [the attorney] exceeded his role as legal counsel"). And when courts have permitted antitrust claims to proceed against a lawyer, it is because the lawyer "ma[de] policy decisions for the corporation" analogous to "the case of any executive officer of the company." *Tillamook Cheese & Dairy Ass'n v. Tillamook County Creamery Ass'n*, 358 F.2d 115, 118 (9th Cir. 1966).

The allegations here do not remotely clear this high bar. Plaintiffs allege that Mr. Insogna "knowingly and intentionally engaged in an anticompetitive scheme" (FAC ¶ 450), but they never assert—much less make plausible, specific factual allegations—that Mr. Insogna "exerted his power and influence so as to direct [Celgene] to engage in the complained of acts for an anticompetitive purpose." *Brown*, 783 F.2d at 646-47. Nor do Plaintiffs contend that Mr. Insogna otherwise did anything other than follow his client's directives and act on behalf of his client, as any lawyer typically would. Indeed, Plaintiffs themselves have acknowledged that Mr. Insogna was simply acting "in service of" what was allegedly "*Celgene*'s scheme." Dkt. 100 at 3 (emphasis added). That is not sufficient to meet the stringent standard for attorney liability under the antitrust laws.

Any other conclusion would set a dangerous precedent that would risk chilling attorneys' zealous advocacy. Lawyers might be inhibited in advancing and executing upon their clients' strategies if they bore a risk of personal liability (or even just lengthy litigation) whenever a plaintiff decided to accuse their client of having acted anticompetitively. Rules of antitrust liability generally must account for this "distinct possibility of overdeterrence," where beneficial conduct "might be shunned by [individuals] who chose to be excessively cautious in the face of uncertainty." *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 441 (1978). Indeed, that is more broadly why "in the absence of special circumstances it is the corporation, not its owner or officer, who is the principal or employer, and thus subject to vicarious liability for torts committed by its employees or agents." *Meyer v. Holley*, 537 U.S. 280, 286 (2003).

Even Plaintiffs do not seriously disagree with this. In their pre-motion letter, Plaintiffs argued that their claims against Mr. Insogna were appropriate under *Jarrow Formulas, Inc. v. Int'l Nutrition Co.*, 175 F. Supp. 2d 296, 314-15 (D. Conn. 2001). *See* Dkt. 100 at 2 n.3. But that

pre-Twombly case allowed an antitrust claim against a lawyer to proceed only because the complaint "include[d] numerous allegations of actions taken by [the lawyer] which exceeded his role as legal advisor," such as "formulating strategy in connection with the scheme to monopolize." Jarrow Formulas, 175 F. Supp. 2d at 314-15 (emphasis added). That is the same standard set forth by Brown and the other cases cited above. And Jarrow Formulas helps only Mr. Insogna, not Plaintiffs, because it shows that Plaintiffs must do far more than allege that Mr. Insogna engaged in patent prosecution for Celgene. Even if Celgene could be liable for this conduct—which it cannot, as explained in Celgene's separate motion to dismiss—there is no basis to pursue that theory against Celgene's lawyer in his personal capacity.

This is presumably why we have not found a *single* case in which a patent attorney—let alone outside counsel—was held personally liable under the Sherman Act or analogous state laws for improperly securing a patent on a client's behalf, even though patent attorneys necessarily play a role in any patent prosecution. Nor, as far as we can tell, have Plaintiffs or their counsel ever pursued this theory against a lawyer previously, even though they regularly allege "fraud on the PTO" as part of antitrust cases.<sup>3</sup> It is thus hard to see their decision to add Mr. Insogna as anything other than a personal attack on Celgene's outside counsel—perhaps in the hope that it might chill the advocacy that Celgene receives from its lawyers—and an attempt to end-run having to justify third-party discovery from him.

<sup>&</sup>lt;sup>3</sup> For instance, after the conclusion of Hatch-Waxman litigation, Plaintiffs' counsel have brought many other antitrust cases in this Circuit that, like this case, were based on a *Walker Process* theory. *None* of these suits included claims against individual lawyers. *See Meijer, Inc. v. Allergan, Inc.* No. 1:19-cv-02563 (E.D.N.Y.); *KPH Healthcare Servs., Inc. v. Allergan*, No. 1:18-cv-00974 (E.D.N.Y.); *Ahold USA, Inc. v. Allergan, Inc.*, No. 1:18-cv-00973 (E.D.N.Y.); *Rochester Drug Co-Operative, Inc. v. Allergan, Inc.*, No. 1:18-cv-00970 (E.D.N.Y.); *FWK Holdings, LLC v. Allergan, Inc.*, No. 1:18-cv-00677 (E.D.N.Y.); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, No. 1:18-md-02819 (E.D.N.Y.); *In re Actos Direct Purchaser Antitrust Litig.*, No. 1:15-cv-03278 (S.D.N.Y.); *In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516 (D. Conn.).

In their pre-motion letter, Plaintiffs also argued that Mr. Insogna's status as a lawyer "does not shield him from accountability" in light of *GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 1323 (Fed. Cir. 2020). Dkt. 100 at 3 & n.5. But *GS Cleantech* holds merely that *a patent* can be "unenforceable due to inequitable conduct" by an attorney. 951 F.3d at 1323. Nothing about *GS Cleantech* suggests that an attorney can be personally liable under antitrust law after a patent is found legally unenforceable—much less *before* any such finding, where (as here) the patents remain valid and enforceable.

But even if one pretended Mr. Insogna were not a lawyer, Plaintiffs' allegations still fall far short of suggesting he could be individually liable for Celgene's supposed scheme. Plaintiffs contend that Mr. Insogna allegedly "participated" in what Plaintiffs claim is "Celgene's scheme to monopolize the market for pomalidomide." Dkt. 100 at 2-3.4 Even for non-lawyers, simply "participating" in another party's purported scheme is not enough to be liable for monopolization. Instead, much as with lawyers, the plaintiff must plead and ultimately prove that "the defendant exerted influence over corporate decisions to the point that his influence shaped corporate intentions." *In re Se. Milk Antitrust Litig.*, 801 F. Supp. 2d 705, 739 (E.D. Tenn. 2011) (granting summary judgment to individual defendant and explaining that plaintiffs had "attempted to evade" the standard for individual liability "by arguing that simple participation in the unlawful acts is sufficient"); *see also, e.g., U.S. Bd. of Oral Implantology v. Am. Bd. of Dental Specialties*, 390 F.

<sup>&</sup>lt;sup>4</sup> In their pre-motion letter, Plaintiffs disclaimed any stand-alone monopolization claim against Mr. Insogna, conceding that Mr. Insogna does not himself possess "monopoly power." *See, e.g., Boulevard Souveniers v. Elvis Presley Enters., Inc.*, 2007 WL 9705982, at \*2 (W.D. Tenn. Oct. 2, 2007) (dismissing monopolization claim against officer of a company because, "as an individual, she d[id] not possess monopoly power"); *In re Mushroom Direct Purchaser Antitrust Litig.*, 514 F. Supp. 2d 683, 699 (E.D. Pa. 2007) (dismissing monopolization claim because the complaint contained "no allegations regarding the monopoly power of the individual member defendants"). Plaintiffs also rightly disclaimed any "stand-alone *Walker Process*" claim against Mr. Insogna. Dkt. 100 at 2.

Supp. 3d 892, 904 (N.D. Ill. 2019) (dismissing claims against individual defendant where, "[a]t most, the complaint alleges that [she] *participated in* the denial of the [Plaintiffs'] application" for specialty certification (emphasis added)).

Thus, in *F.T.C. v. Vyera Pharms., LLC*, 479 F. Supp. 3d 31 (S.D.N.Y. 2020), which Plaintiffs' pre-motion letter cited, *see* Dkt. 100 at 2 n.2, the court held that the founders of the defendant pharmaceutical company (who were also among its corporate executives) could potentially be liable as individuals because they "not only participated in the anticompetitive conduct at issue, but also designed, implemented, and negotiated the network of contracts that block generic competition" for the company's drug. 479 F. Supp. 3d at 50. *Vyera* does not support imposing liability on a defendant who was *not* an architect of the alleged anticompetitive scheme, had no role in selling the allegedly monopolized product, and allegedly helped implement one portion of the supposed scheme.

Similar to the reasons why Plaintiffs have failed to meet the standard for holding a lawyer liable under the antitrust laws, then, Plaintiffs' allegations about Mr. Insogna fall short of stating a basis for individual monopolization liability. There are no allegations—much less plausible, specific factual allegations—that Mr. Insogna designed the alleged anticompetitive scheme or did anything similar. Instead, the allegations are only that Mr. Insogna participated in one aspect of this purported scheme. Certainly Plaintiffs allege nothing comparable to the allegations that sufficed in *Vyera*. The Court should accordingly dismiss the claims against Mr. Insogna.<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Plaintiffs have not brought a conspiracy claim, and the complaint's vague allusions to "conspiracy" (FAC ¶¶ 14, 16) are thus irrelevant. Nor could a conspiracy claim stand here when, among other things, the complaint does not allege that Mr. Insogna had "the specific intent to achieve an unlawful monopoly" or entered into any agreement in furtherance of such a monopoly. *In re Inclusive Access Course Materials Antitrust Litig.*, 544 F. Supp. 3d 420, 439 (S.D.N.Y. 2021) (quoting *AD/SAT*, *Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 233 (2d Cir. 1999).

## B. Plaintiffs Do Not Allege That Mr. Insogna Participated in a Scheme to Monopolize.

Separately, Plaintiffs' claims also fail because, at most, they pleaded that Mr. Insogna was involved in a scheme *to obtain patents*—not a scheme to enforce them, and not an alleged scheme to improperly settle cases with generic manufacturers to delay competition. Plaintiffs' core theory as to Mr. Insogna is that he helped Celgene procure patents through what Plaintiffs falsely contend was fraudulent conduct. FAC ¶ 11. That is all. But merely obtaining patents—even if improperly done—is insufficient to plead a monopolization claim based on *Walker Process*, which instead turns on how the patentee (not its individual lawyers) *leveraged* those patents. *See Walker Process*, 382 U.S. at 177; *Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153, 1161-62 (Fed. Cir. 1996), *abrogated on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998)); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 517 n.3 (E.D.N.Y. 2005) (antitrust claim based on *Walker Process* requires that "the other elements of a Sherman Act claim are present"); Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 706a2 (Aug. 2023 update). And the Complaint does not allege that Mr. Insogna played *any* role in any improper enforcement strategy.

Moreover, the doctrine of intra-corporate conspiracy would bar a conspiracy claim when Mr. Insogna was always acting as Celgene's agent. See Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 769 (1984) (rejecting conspiracy claim because "officers of a single firm are not separate actors"); Potters Med. Ctr. v. City Hosp. Ass'n, 800 F.2d 568, 573-74 (6th Cir. 1986) (applying Copperweld to hold that physician and attorney could not conspire with their hospital employer to violate Sherman Act); U.S. Bd. of Oral Implantology, 390 F. Supp. 3d at 904, 907 (applying Copperweld to dismiss Sherman Act conspiracy claims against organization's individual directors); In re Aluminum Warehousing Antitrust Litig., 95 F. Supp. 3d 419, 445 (S.D.N.Y. 2015) ("To the extent agents are merely carrying out the decisions of principals, they are not separate entities ...."). An antitrust conspiracy requires "separate economic actors pursuing separate economic interests." Am. Needle, Inc. v. Nat'l Football League, 560 U.S. 183, 195 (2010) (citation omitted) (emphasis added).

To suggest otherwise in their pre-motion letter, Plaintiffs identified a single case where Mr. Insogna was listed as "Of Counsel" for the third of three law firms and the fifth of eight attorneys appearing on behalf of Celgene on a complaint. *See* Dkt. 100 at 2 n.4 (citing *Celgene v. Hetero*, No. 17-cv-03387 (D.N.J.), ECF No. 1). But simply appearing for a client in court does not show *Walker Process* "enforcement"—particularly when the Complaint lacks any allegations about this single case or Mr. Insogna's role in it. *See Iqbal*, 556 U.S. at 678 ("The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully.").

Moreover, when Mr. Insogna allegedly first started his patent-prosecution work for the two patents at issue, Celgene was years away from receiving FDA approval for POMALYST®—and had yet to even obtain all of its pomalidomide patents. The Complaint does not allege that Celgene had conceived of an improper scheme to monopolize the pomalidomide market long before that market even existed, and before Celgene had even obtained approval to sell a pomalidomide drug. And the Complaint does not plead that Mr. Insogna was even aware of any such scheme, much less that he developed the scheme or that it existed when he was prosecuting the patents. *See Schmitt v. FMA Alliance*, 398 F.3d 995, 997 (8th Cir. 2005) (holding that "while the knowledge of the agent is imputed to the principal, the converse is not true"). Plaintiffs' underbaked "participation" theory thus does not remotely suffice to state a claim against Mr. Insogna, because it does not even connect him to a purported scheme to monopolize.

# C. Plaintiffs Have Failed to Plausibly Plead with Particularity That Mr. Insogna Engaged in *Walker Process* Fraud.

As explained in detail in Celgene's motion to dismiss, Plaintiffs also fail to plead the additional elements demanded under *Walker Process*—namely, that the defendant intentionally deceived the PTO, and that the patent otherwise would not have issued. *See, e.g., C.R. Bard, Inc.* v. *M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). Moreover, *Walker Process* claims must

allege these elements in accordance with "the heightened pleading standards of Rule 9(b)." *Radiancy, Inc. v. Viatek Consumer Prods. Grp., Inc.*, 138 F. Supp. 3d 303, 324 (S.D.N.Y. 2014). This means that "the circumstances constituting fraud or mistake shall be stated with particularity." *Id.* (quoting Fed. R. Civ. P. 9(b)). As the Federal Circuit has explained, the bar for pleading fraud on the PTO is set deliberately high so that such allegations do not "devolve into a magic incantation to be asserted against every patentee." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1331 (Fed. Cir. 2009).

Plaintiffs disregard this principle by lumping Mr. Insogna in with the other defendants, as if they were all interchangeable. *See, e.g.*, FAC ¶¶ 170, 173, 174, 175, 176, 187, 188, 189, 191, 193 (making allegations against "Celgene (along with Insogna and Zeldis)"). But "plaintiffs may not use collective references . . . [that] blur important distinctions among defendants and evade the requirement that fraud be pled with particularity." *Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 446 F. Supp. 2d 163, 187 n.167 (S.D.N.Y. 2006).

In any event, even ignoring Plaintiffs' improper group pleading, their allegations utterly fail to show that Mr. Insogna engaged in any supposed misconduct—separate and apart from the fact that he also never enforced the patents, which is independently dispositive under *Walker Process*. Plaintiffs do not adequately allege that Mr. Insogna engaged in *any* fraudulent conduct. Celgene Br., Dkt. 109, at 26-38, 40-42. Nor do Plaintiffs adequately allege that this fictional misconduct actually *caused* the PTO to issue relevant patents. *Id.* at 32-34, 37-38, 41-42. Mr. Insogna fully joins Celgene's motion to dismiss on these and all other points.

But Plaintiffs' theory that Mr. Insogna "lied, repeatedly," to the PTO is far worse than meritless. *See* Dkt. 100 at 3. It is also inflammatory and demonstrably false. These are serious accusations squarely refuted by public records to which Plaintiffs have full access—yet Plaintiffs

have nevertheless sought to smear Mr. Insogna's name in this action. Mr. Insogna does not take this matter lightly, and neither should Plaintiffs.

#### II. PLAINTIFFS' CLAIMS AGAINST MR. INSOGNA ARE TIME-BARRED.

Plaintiffs' claims against Mr. Insogna are also untimely. Untimely claims should be dismissed under Rule 12(b)(6) when it is "clear from the face of the complaint, and matters of which the court may take judicial notice, that the plaintiff's claims are barred as a matter of law." Staehr v. Hartford Fin. Servs. Grp., Inc., 547 F.3d 406, 425 (2d Cir. 2008) (emphasis omitted).

Plaintiffs agree that a four-year statute of limitations applies to their Sherman Act claims. *See* Dkt. 100 at 3 & n.6 (citing 15 U.S.C. § 15(b)). But here, Mr. Insogna's last alleged act was in *June 2013*, when Plaintiffs allege that Mr. Insogna submitted data in response to the examiner's rejection of the '427 patent. FAC ¶ 213. And the first lawsuits against ANDA filers based on the '262 and '427 patents were filed in May 2017. Accordingly, all of Mr. Insogna's alleged anticompetitive acts, and even the purported exclusion based on those alleged acts, occurred more than four years before Plaintiffs named Mr. Insogna as a defendant. Plaintiffs' Sherman Act claims against Mr. Insogna are time-barred as a result. The same is true for Plaintiffs' state-law claims. *See* Zeldis Br., Dkt. 115, at Exh. (collecting state laws).

In their pre-motion letter, Plaintiffs argued that their claims accrued in October 2020, because that is "when Aurobindo and Natco/Breckenridge received final [FDA] approval and would have launched lower-priced generic Pomalyst, absent the unlawful settlement agreements with Celgene." Dkt. 100 at 3 (citing FAC ¶ 309). According to Plaintiffs, that FDA approval date is the earliest they could have "brought their suit for damages caused by delayed generic entry." *Id.* But that rule of accrual applies only to claims that the defendant overcharged for a product. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 295 (2d Cir. 1979). It cannot apply to Mr. Insogna, who is not a monopolist and cannot "overcharge" anyone.

For similar reasons, *In re Aggrenox Antitrust Litigation*, 94 F. Supp. 3d 224, 237 (D. Conn. 2015), which Plaintiffs cited in their pre-motion letter, is inapposite. *See* Dkt. 100 at 3 & n.6. At most, that case suggests that plaintiffs can sometimes sue a "monopolist" who is "continu[ing] to use the power it has gained illicitly to overcharge its customers" during the limitations period. *Aggrenox*, 94 F. Supp. 3d at 237. It does not allow Plaintiffs to sue *Mr. Insogna*, who cannot be a "monopolist" and is not "overcharg[ing]" anyone, for damages based on conduct that happened over a decade ago.

## III. PLAINTIFFS' STATE-LAW CLAIMS AGAINST MR. INSOGNA ALSO FAIL ON THE MERITS.

#### A. Plaintiffs Have Failed to State a Claim Against Mr. Insogna Under State Law.

Plaintiffs list 28 state statutes in Count Five, but fail to set out the elements of those statutes or how Mr. Insogna's conduct allegedly violates them. FAC ¶¶ 460-72. Moreover, Plaintiffs do not even mention Mr. Insogna in the paragraph setting forth their allegation that Celgene "intentionally and flagrantly violated" this laundry list of state statutes. *Id.* ¶ 471. Basic pleading standards "require[] more than labels and conclusions," *Twombly*, 550 U.S. at 555, and here Plaintiffs offer even less against Mr. Insogna for these state-law claims.

## B. Plaintiffs' State-Law Claims Fail for the Same Reasons as Their Federal Claims.

Plaintiffs rely on the same alleged conduct for the purported violations of state law. They allege that "Celgene and Bristol Myers" violated these statutes, but at most plead that Mr. Insogna "worked for Celgene" and "engaged in an anticompetitive scheme," and that they can therefore recover "overcharges" against him. FAC ¶¶ 465-66. For the reasons stated above, these claims should be dismissed, as these state statutes should be interpreted in accordance with corresponding federal law. *See, e.g., In re Magnesium Oxide Antitrust Litig.*, 2011 WL 5008090, at \*7 n.9 (D.N.J. Oct. 20, 2011) (dismissing Arizona, California, District of Columbia, Illinois, Iowa, Kansas,

Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin antitrust claims because those states' laws "are construed in accordance with federal antitrust principles"); *Vacco v. Microsoft Corp.*, 260 Conn. 59, 65 (Conn. 2002) (same as to Connecticut); Haw. Rev. Stat. § 480-3 (same as to Hawai'i); Md. Code, Com. Law § 11-202(a)(2) (same as to Maryland); R.I. Gen. Laws § 6:36-2(b) (same as to Rhode Island).

#### **CONCLUSION**

The Court should dismiss the claims against Mr. Insogna in their entirety.

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